



Regulation (EU) 2017/745, Annex XI Part A

MDR 720081 R000

Manufacturer: STIMULI TECHNOLOGY

Address:

20 bis rue Barthélémy Danjou Boulogne Billancourt 92100 France

Single Registration Number: Not Available

Scope: See attached Device Schedule

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

Gary C Stade

First Issued: **2021-02-02** Date: **2021-02-02** Expiry Date: **2026-02-01**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.





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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification	A RECEIPT
TENSI+ (Neuromuscular electro stimulator)	Class IIa	



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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





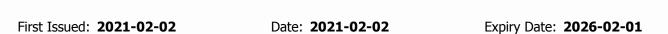
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate. Verification@bsigroup.com)

Date	Reference number	Action
Current	3095636	Initial Issue



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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 720081 R000

Date: 2021-02-02

Critical Subcontractor/Crucial Supplier

BSE Electronics 616 avenue de l'Europe BP 87 Le Creusot 71200 France

Service(s) supplied

Assembly
Final Inspection
Labelling
Manufacture

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